Louisiana Medicaid
Givosiran (Givlaari™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for givosiran (Givlaari™).

Additional Point-of-Sale edits may apply.

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- Givosiran (Givlaari™) is prescribed by, or the request states that this medication is being prescribed in consultation with, a specialist with expertise in the diagnosis and management of acute hepatic porphyria (AHP), such as a hematologist or gastroenterologist; **AND**
- The recipient has a diagnosis of acute hepatic porphyria (AHP); **AND**
- The recipient has had at least **TWO** documented porphyria attacks within the 6-month period before the date of the initial request that required either hospitalization, urgent healthcare visit or intravenous hemin administration at home, and the medical service(s) utilized with dates of service are **stated on the request**; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial authorization approval: 12 months

Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

Reference

Givlaari (givosiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals; November 2019. https://www.alnylam.com/wp-content/uploads/pdfs/GIVLAARI-Prescribing-Information.pdf

Revision	Date
Policy created	July 2020